

**TITLE 16: BOARD OF PHARMACY**  
**FINAL STATEMENT OF REASONS**

**Subject Matter of Proposed Regulations:** Naloxone Fact Sheet

**Section Affected:** Amend Title 16 California Code of Regulations (CCR) section 1746.3

**Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on April 26, 2019, and ended on June 17, 2019. The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the board during the 45-day comment period.

During the 45-day comment period no comments were received. On June 21, 2019, the board adopted the regulation text as noticed on April 26, 2019.

**Local Mandate**

A mandate is not imposed on local agencies or school districts.

**Small Business Impact**

While the board does not have, nor does it maintain, data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the board has made the determination that this proposal will not have a significant adverse impact directly affecting small businesses. The proposed regulation will assist all businesses, including small businesses, in streamlining processes and reducing duplication of work when naloxone hydrochloride is furnished by a pharmacist.

**Consideration of Alternatives**

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private person and equally effective in implementing the

statutory policy or other provision of law. The board considered the following alternative:

The only alternative to this proposal is to not amend the requirements. This alternative was rejected because the change in regulation can increase patient education and medication adherence and assist licensees in streamlining business processes.

### **Objections or Recommendations/Responses to Comments**

#### 45-Day Public Comment Period

During the 45-day public comment period from April 26, 2019 to June 17, 2019, the board received zero comments.

At its June 21, 2019 meeting, the board voted to adopt the regulation text as it was noticed on April 26, 2019.